# CLINICAL TO COMMERCIAL













Development & Manufacturing

### THE CUSTOM DIFFERENCE

Established in 1979, Custom Pharma Services has grown to become the go-to resource for contract development, manufacturing and packaging solutions in the United Kingdom and across Europe.

Offering end-to-end support from clinical trials to commercialisation, our experienced development team can create innovative options tailored to your individual needs. Custom has a well-deserved reputation for finding unique, groundbreaking solutions for even the most niche pharmaceutical products.

Led by a team of seasoned professionals with decades of pharmaceutical experience, our staff includes chemists and scientists as well as highly qualified process engineers, quality assurance specialists and project management experts. Custom is fully certified in the UK and Europe, employing an experienced clinical and product development team offering innovative solutions, including customised commercial manufacturing and packaging capabilities.

You have a lot invested in your compound, which means that choosing a partner to help you bring it to market is one of the most critical decisions you'll make. When you need a partner that can help with concepting, process and formulation development, prototypes, stability and analytical testing, certification, contract manufacturing, primary packaging, shipment, consultancy and customer support, Custom Can!



For more than 35 years, we have continually expanded our scope of services to prove that no matter what you need, Custom Can!"

- Dr. Iain McGroarty, Director of Business Development

#### AN OVERVIEW OF OUR SERVICES

## When you need a partner that can make a difference to your bottom line, Custom Can!



Our team works independently or as part of your team in our advanced product development facilities.



More than 35 years of experience manufacturing a wide range of solid dose, powders and hard gel capsules.



Fast, efficient and cost-effective solutions for a wide range of packaging needs.



Hands-on managers ensuring you meet time, budgetary and technical requirements at every stage.



#### **CLINICAL & PRODUCT DEVELOPMENT**

Need someone to ramp up from small batch and pilot? Custom Can!



Pharma developers are ready to bring their products to life, and we're ready to provide unique solutions to make that happen."

Nigel Richardson, CEO

#### **EXPERIENCED, END-TO-END**

Custom's expert chemists, scientists and process engineers — many with decades of experience in the pharmaceutical industry — have extensive preformulation and formulation expertise as well as production experience with investigational medicinal products (IMPs) for clinical trials. We can guide you through your entire project or step in at any point where you need us.

Custom is your one-stop shop. From manufacturing small batches for clinical trials to ramping up for mass production and worldwide distribution, **Custom Can!** 

#### Preformulation:

- Solubility/stability assessment
- Excipient screening
- API properties for processability

#### Formulation development:

- Solid dose
- Tablets
- Capsules, hard gel
- Immediate and modified release
- Powders
- Reverse formulation engineering
- Clinical trial supply engineering
- Clinical to commercial scale up

- Modified release
  - Buccal delivery
  - · Enteric coating
  - Semi-permeable coating
  - Sugar coating
  - Polymer matrices
  - Multi-stage granulations
  - Chewable preparations
- Process optimisation and validation

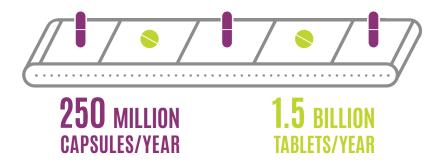


When you need someone to manufacture your solid dose, hard gel capsules and powders, Custom Can!

#### STATE-OF-THE-ART CAPABILITIES

Custom Pharma Services has manufactured a wide range of solid dose, powders and hard gel capsules for branded and generic pharmaceuticals since 1979. Our facilities can manufacture existing and new formulations, and we provide innovative solutions for your hard-to-manufacture niche products.

We have licences for the manufacture of hormones, controlled drugs, specials and investigational medicinal products (IMPs). Our facilities and services are certified by the Medicines and Healthcare products Regulatory Agency (MHRA).







Need a partner that can offer a full range of packaging options? Custom Can!



With our state-of-the-art facility and equipment, we can meet the needs of any customer. Flexibility is crucial in this industry, and we are just that."

— Barbara Easton, Operations Director

#### THE COMPLETE PACKAGE

Custom's clinical and commercial operations are supported by project managers and logistics experts, working with adaptable primary packaging lines that enable clinical, commercial or stability blister and bottle packaging.

- 4,000-square-meter packaging facilities
- 1,700-square-meter, temperature-monitored warehouse

- Blister packing capacity of 50+ million blisters per year
- Large range of tooling

#### **Packaging options:**

- Clinical, commercial and stability packaging
- PVC/PVDC, ALU/ALU (including cold form), ACLAR
- Bottle filling and labelling

- Tamper-evident sealing
- Serialisation in line with current legislation timing



**PROJECT MANAGEMENT** 

If you're looking for a company that can excel in customer service, Custom Can!



Excellent customer service is the driving force behind our business, and project management is the vehicle that ensures all aspects of your programme are executed flawlessly."

— Dr. Iain McGroarty, Director of Business Development

#### ON TIME AND ON BUDGET

Custom Pharma Services project managers form a critical part of each project, ensuring that every programme is delivered on time and in full. Your project manager will coordinate every process in each phase of your programme to meet your timelines and budget.

Our project managers all have more than a decade of experience within the pharmaceutical industry, having managed programmes from both clinical and commercial sectors. As a key member of your product and process development team, your project manager will ensure all your technical requirements are met and will work with you to resolve any regulatory challenge you encounter.

We consider it an honour to help bring lifesaving and life-enhancing products to the world. That's why our project managers treat every programme as if it is their own. We will communicate with you at every stage, updating you on the progress of your project throughout the development cycle and responding quickly and appropriately to your special needs.



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